NATIONAL GUI DELI NE CLEARI NGHOUSE™ (NGC) GUI DELI NE SYNTHESI S

TOBACCO USE CESSATION AND PREVENTION

Guidelines

- 1. Public Health Service (PHS). <u>Treating tobacco use and dependence.</u> Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. 197 p. [311 references]
- 2. University of Michigan Health System (UMHS). <u>Smoking cessation.</u> Ann Arbor (Michigan): University of Michigan Health System, 2001. 9 p. [1 reference]
- 3. Singapore Ministry of Health (MOH). <u>Smoking cessation.</u> Singapore: Singapore Ministry of Health; 2002 Apr. 33 p. [82 references]
- New Zealand Guidelines Group (NZGG). <u>Guidelines for smoking cessation:</u> <u>revised 2002</u>. Wellington (New Zealand): National Advisory Committee on Health and Disability (National Health Committee); 2002 May. 33 p. [42 references]
- 5. U.S. Preventive Services Task Force (USPSTF). <u>Counseling to prevent tobaccouse and tobacco-caused disease: recommendation statement.</u> Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003 Nov. 13 p. [22 references]

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INTRODUCTION:

A direct comparison of PHS, UMHS, Singapore MOH, NZGG, and USPSTF recommendations for tobacco use cessation and prevention is provided in the tables below. <u>Table 1</u> provides the scope of the guidelines, <u>Table 2</u> compares the major recommendations, and <u>Table 3</u> compares the potential benefits and harms of implementing the recommendations. Definitions for the levels of evidence used to support the guideline recommendations are given in <u>Table 4</u>; references supporting the Singapore MOH recommendations are also provided in this table.

The comparison in <u>Table 2</u> is restricted to recommendations for interventions to be carried out by physicians and/or other health care professionals. PHS also gives recommendations on interventions to be used by health systems and on the economic aspects of tobacco use cessation that are not addressed in this comparison. The NZGG guideline also contains many recommendations specific to the Maori population of New Zealand. The user is directed to the individual guidelines for information on these recommendations.

Following the tables and discussion of content comparison, the areas of agreement and differences among the guidelines are identified. In general, the timing of guideline development with respect to available data is an important factor to consider when evaluating areas of differences among the guidelines. Interpretation of available data is also considered.

Related Guidelines

Centers for Disease Control and Prevention/Task Force on Community Preventive Services. <u>Strategies for reducing exposure to environmental tobacco smoke, increasing tobacco-use cessation, and reducing initiation in communities and health-care systems.</u> Am J Prev Med 2001 Feb; 20(2 Suppl): 10-5 [21 references].

Listed below are common abbreviations used within the tables and discussions:

- AHRQ, Agency for Healthcare Research and Quality
- FDA, Food and Drug Administration
- MOH, Ministry of Health (Singapore)
- NRT, Nicotine replacement therapy
- NZGG, New Zealand Guideline Group
- PHS, Public Health Service (United States)
- UMHS, University of Michigan Health System
- U.S., United States
- USPSTF, United States Preventive Services Task Force

TABLE 1: SCOPE	
Objectives	
PHS	To provide evidence-based recommendations along with a

(2000)	simple and flexible set of strategies that ensure that all patients who use tobacco are offered motivational interventions and effective treatments to overcome tobacco addiction To include new effective clinical treatments for tobacco dependence that have become available since the 1996 AHRQ guideline was developed
UMHS (2001)	To provide a systematic framework for care providers to assist patients in smoking cessation
SINGAPORE MOH (2002)	To provide recommendations for smoking abstinence
NZGG (2002)	 To increase the quit rate among smokers seen by health workers Specific Aims To reinforce the importance of smoking as a preventable adverse health factor To promote the integration of smoking cessation interventions into routine clinical care throughout the health system To improve the information and support given people who want to stop smoking To ensure all health workers feel confident in the advice they give and the resources available to support smoking cessation To promote the use of nicotine replacement therapy, as an adjunct to ongoing support for people attempting to quit
USPSTF (2003)	 To summarize the USPSTF recommendations on counseling to prevent tobacco use and tobacco-caused disease and the supporting scientific evidence To update the 1996 recommendations contained in the Guide to Clinical Preventive Services, Second Edition
	Target Population
PHS (2000)	 United States The guideline addresses treatment and prevention in the

	following groups:		
UMHS (2001)	 United States The guideline focuses primarily on adult smokers; adolescents are addressed in the context of special populations. 		
SINGAPORE MOH (2002)	 Singapore Adult smokers (children and adolescent tobacco users are not addressed in this guideline) 		
NZGG (2002)	 New Zealand Smokers in New Zealand, including pregnant women, children and adolescents, and native Maori people 		
USPSTF (2003)	 United States General population, including adults, pregnant women, and children, seen in primary care settings 		
	Intended Users		
PHS (2000)	Advanced Practice Nurses, Allied Health Personnel, Dentists, Health Plans, Managed Care Organizations, Nurses, Pharmacists, Physical Therapists, Physician Assistants, Physicians, Psychologists/Non-physician Behavioral Health Clinicians, Respiratory Care Practitioners		
UMHS (2001)	Health Care Providers, Physicians		
SINGAPORE MOH (2002)	Advanced Practice Nurses, Dentists, Health Care Providers, Hospitals, Nurses, Pharmacists, Physician Assistants, Physicians, Psychologists/Non-physician Behavioral Health Clinicians		
NZGG (2002)	Advanced Practice Nurses, Allied Health Personnel, Dentists, Health Care Providers, Nurses, Pharmacists, Physician Assistants, Physicians, Psychologists/Non-physician Behavioral Health Clinicians, Public Health Departments, Respiratory Care Practitioners, Substance Use Disorders Treatment Providers		
USPSTF	Advanced Practice Nurses, Nurses, Physician Assistants,		

(2003)	Physicians, Public Health Departments
	Interventions And Practices Considered
PHS (2000)	Screening to identify and document tobacco use status
	Counseling and patient education, including:
	 "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange) 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)
	Pharmacotherapy:
	 First-line: Bupropion SR (sustained-release bupropion) Nicotine gum Nicotine inhaler Nicotine nasal spray Nicotine patch Second-line: Clonidine Nortriptyline Combination Therapy
	Prevention strategies
	 Relapse prevention treatment (counseling and pharmacologic) Encouraging children and adolescents to stay abstinent
	Coordination of care
	Tailoring of treatments to special populations
	Advice on weight gain after smoking cessation
	Advice on non-cigarette tobacco products
	Clinician training in strategies to assist tobacco users in quitting
UMHS (2000)	Screening to identify and document tobacco use status
(2333)	Counseling and patient education, including:
	 "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange) 4 R's (relevance, risk, rewards, repetition) motivational

	intervention for users not ready to quit
	Pharmacotherapy:
	 First-line: Bupropion SR (sustained-release bupropion) Nicotine gum Nicotine inhaler Nicotine nasal spray Nicotine patch Second-line: Clonidine Nortriptyline Combination Therapy
	Follow-up to prevent relapse
	Tailoring of treatments to special populations
	Advice on weight gain after smoking cessation
	Advice on non-cigarette tobacco products
SINGAPORE MOH	Screening to identify and document tobacco use status
(2002)	Counseling and patient education, including:
	 "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange) 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)
	Pharmacotherapy:
	 Nicotine replacement therapy (NRT), including nicotine patch (available as 24-hour and 16-hour patches) or nicotine inhaler Bupropion hydrochloride slow release (SR)
	 Other drugs, such as clonidine and nortriptyline, as second- line therapy
	Combination therapyDrug therapy during pregnancy
	Counseling and behavior therapy used in conjunction with pharmacotherapy
NZGG (2002)	Screening to identify and document tobacco use status

Counseling and patient education, including:

- "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)
- 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)
- Telephone quitlines and Aukati Kai Paipa (smoking cessation service)

Pharmacotherapy:

- First-line:
 - Nicotine replacement therapy (NRT), including nicotine gum, nicotine nasal spray, nicotine patch, nicotine inhaler
- Second line:
 - o Bupropion
 - o Nortriptyline
- Combination therapy

Special considerations for high-risk groups:

- Pregnant women
- Children and adolescents
- Other high-risk populations within New Zealand, including Maori

Smoking cessation training for health professionals

USPSTF (2003)

Screening to identify and document tobacco use status

Counseling and patient education, including:

- "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)
- 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)
- Telephone quitlines
- Augmented pregnancy-tailored counseling
- Self-help materials

Pharmacotherapy, including:

- Nicotine replacement therapy (i.e., nicotine gum, nicotine transdermal patches, nicotine inhaler, and nicotine nasal spray)
- Sustained-release bupropion
- Clonidine
- Nortriptyline

•	Combination	therapy
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TABLE 2: RECOMMENDATIONS FOR TOBACCO USE CESSATION AND PREVENTION	
SCREENING AND ASSESSMENT	
	Screening for tobacco use
PHS (2000)	All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis (Strength of Evidence = A).
	Clinic screening systems such as expanding the vital signs to include tobacco-use status, or the use of other reminder systems such as chart stickers or computer prompts are essential for the consistent assessment, documentation, and intervention with tobacco use (Strength of Evidence = B).
UMHS (2001)	Ask all patients about smoking status and assess smoker's readiness to quit.
	Smoking status should be documented in the medical record. Techniques to remind the physician of a patient's smoking status include smoking status stickers, listing tobacco use on active problem list of tobacco status as part of vital signs.
SINGAPORE MOH (2002)	All patients should be asked if they use tobacco and should have their tobacco use status documented on a regular basis. Clinicians and health care delivery systems should institutionalise the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting (Chang, Zimmerman, & Beck, 1995; National Cancer Institute, 1994; Ockene, 1987; Pederson, Baskersville, & Wanklin, 1982; Robinson, Laurent, & Little, 1995; Yarnall et al., 1998). (Grade A, Level Ia, Ib)
	For example: Expand the vital signs to include tobacco use. Place tobacco use stickers on patient records. Indicate tobacco use status in electronic medical records or computer reminder systems.
NZGG (2002)	The smoking status of every adult should be identified and prominently documented in the medical record. For current smokers and those who have quit in the past year, smoking

	status should be updated at each visit.
	Place a smoking status and/or second-hand smoke sticker on the master problem list, or electronically document in computerised notes.
	For identified smokers and recent quitters (within one year), update smoking status at each visit.
USPSTF (2003)	The USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products (A recommendation).
	Clinics that implement screening systems designed to regularly identify and document a patient's tobacco use status increased their rates of clinician intervention, although there is limited evidence for the impact of screening systems on tobacco cessation rates.
	Willingness to quit and motivational strategies
PHS (2000)	Once a tobacco user is identified and advised to quit, the clinician should assess the patient's willingness to quit at this time (Strength of Evidence = C).
	 If the patient is willing to make a quit attempt at this time, effective interventions should be initiated. If the patient is unwilling to quit at this time, a motivational intervention should be provided (e.g., the 5 R's, relevance, risks, rewards, roadblocks, and repetition).
	Tobacco dependence treatment is effective and should be delivered even if specialized assessments are not used or available (Strength of Evidence = A).
UMHS (2001)	Assess whether the patient is "ready to attempt to quit."
(2001)	If "yes," set a quit date, assist by providing personalized advice, pharmacologic therapy as appropriate, and information on community programs, and arrange follow-up.
	If "no," offer motivational interventions using the 4 "R's"
	 Relevance: impact of smoking on current health/illness and/or on children and others in household; economic costs of tobacco use Risks: potential negative consequences of smoking
	 Rewards: improved health, improved taste, money saved Repeat above strategies with unmotivated patients at every

	visit
SINGAPORE MOH (2002)	Once a tobacco user is identified and advised to quit, the health care practitioner should assess the patient's willingness to quit at this time: • Patients willing to try to quit tobacco use should be provided treatments identified as effective in this set of guidelines. • Patients unwilling to try to quit tobacco use should be provided a brief intervention designed to increase their motivation to quit as described in this set of guidelines (e.g., the 5 R's, relevance, risks, rewards, roadblocks, and repetition). (Grade C, Level IV) Motivational intervention Patients unwilling to make a quit attempt may lack information about the harmful effects of tobacco, may lack the required financial resources, may have fears or concerns about quitting, or may be demoralised because of previous failed efforts. Such patients may respond to a motivational intervention such as those built around the 5R's: relevance, risks, rewards,
	roadblocks, and repetition. Motivational interventions are more likely to succeed if the clinician is empathetic, allows patients to make their own choices, does not argue with the patients, and encourages them to believe that they can quit by helping them identify previous successes in their attempts to quit.
NZGG (2002)	Determine the willingness of smokers to make a quit attempt by asking every smoker how they feel about their smoking. The purpose of determining a person's willingness to quit is to enable the most appropriate and beneficial assistance to facilitate smoking cessation.
	Smoking cessation is a process occurring over time. A commonly accepted model is Prochaska & DiClemente's "stages of change," in which smokers are seen as moving through a series of stages: Precontemplative (not considering quitting) TO Contemplative (planning to quit in the next six months) TO Action (ready to quit soon) TO Maintenance/relapse
	If the person clearly states he/she is unwilling to make a quit attempt at this time, provide relevant information and assure

	them that their health care team is available to help when ready.	
	Time permitting, explore barriers to considering quitting and provide motivational interventions as specified in the 5 R's (relevance, risks, rewards, roadblocks, and repetition)	
USPSTF (2003)	Helpful aspects of counseling include providing problem-solving guidance for smokers to develop a plan to quit and to overcome common barriers to quitting and providing social support within and outside of treatment.	
	Common practices that complement this framework include motivational interviewing, the 5 R's used to treat tobacco use (relevance, risks, rewards, roadblocks, repetition), assessing readiness to change, and more intensive counseling and/or referrals for quitters needing extra help. Telephone "quit lines" have also been found to be an effective adjunct to counseling or medical therapy.	
	TREATMENT STRUCTURE AND INTENSITY	
	Advise tobacco users to quit	
PHS (2000)	All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates (Strength of Evidence = A).	
	All clinicians should strongly advise their patients who use tobacco to quit. It is reasonable to believe that such advice is effective in increasing their patients' long-term quit rates (Strength of Evidence = B).	
UMHS (2001)	Advise all smokers to seriously consider making a quit attempt using a clear and personalized message.	
SINGAPORE MOH (2002)	All clinicians should strongly advise every patient who smokes to quit ("Practice guideline," American Psychiatric Association, 1996; Orleans, 1993; US Department of Health and Human Services, 1988). (Grade A, Level Ia)	
NZGG (2002)	Provide brief cessation messages at nearly every encounter. These messages should be: clear, strong and personalized; supportive; and non-confrontational.	
USPSTF (2003)	Advise smokers to quit through clear personalized messages.	
	Intensity of clinical interventions	

PHS (2000)	Tobacco users should be offered at least a minimal intervention (3 minutes or less) whether or not they are referred to an intensive intervention (Strength of Evidence = A).
	Intensive interventions are more effective than less intensive interventions and should be used whenever possible (Strength of Evidence = A).
	If feasible, clinicians should strive to meet four or more times with individuals quitting tobacco use (Strength of Evidence =A).
	Treatment should be delivered by a variety of clinician types to increase abstinence rates (Strength of Evidence = A).
	Treatments delivered by multiple types of clinicians are more effective than interventions delivered by a single type of clinician and are therefore encouraged (Strength of Evidence = C).
UMHS (2001)	Advice as brief as 3 minutes is effective in smoking cessation [C]. In addition to clinician counseling in the office, intensive counseling (frequently defined as a minimum of weekly meeting for the first 4 to 7 weeks of cessation) significantly enhances cessation rates. However, participation in intensive counseling is based largely on patients' motivation to quit and ability to pay [C].
SINGAPORE MOH (2002)	Brief tobacco dependence treatment is effective and every patient who uses tobacco should be offered at least brief treatment. (Grade A, Level IIa)
	There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Intensive interventions are more effective than less intensive interventions and should be used whenever possible. (Grade A, Levels Ia, Ib, IIa)
NZGG (2002)	Brief, repetitive, consistent, positive reminders to quit from multiple providers (or reinforcement of a recent quit attempt) double success rates.
USPSTF (2003)	Brief tobacco cessation counseling interventions, including screening, brief counseling (3 minutes or less), and/or pharmacotherapy, have proven to increase tobacco abstinence rates, although there is a dose-response relationship between quit rates and the intensity of counseling. Effective interventions may be delivered by a variety of primary care clinicians.
Follow-	-up assessment and procedures (prevention of relapse)

PHS All patients who receive a tobacco dependence intervention (2000)should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts. (1) Abstinent patients should receive relapse prevention treatment. (2) Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt (Strength of Evidence = C). Every ex-tobacco user undergoing relapse prevention should receive congratulations on any success and strong encouragement to remain abstinent. **UMHS** Arrange follow-up either with phone call or office visit. Follow-up (2001)contact should occur soon after the quit date, preferably during the first week [C]. Extending treatment contacts over a number of weeks appears to increase cessation rates [D]. Further followup as needed. For abstinent patients, prevent relapse by congratulating successes and reinforcing reasons for quitting. Assess any difficulties with pharmacologic therapy. Patients who relapse should be considered for more intensive counseling or should have their pharmacotherapy reassessed and should be advised to make another quit attempt. SINGAPORE When clinicians encounter a patient who has guit smoking MOH recently, they should reinforce the patient's decision to guit, (2002)review the benefits of quitting, and assist the patient in resolving any residual problems arising from quitting. Although most relapses occur early in the quitting process, some relapses occur months or even years after the quit date. Therefore, clinicians should engage in relapse prevention interventions even with former tobacco users who no longer consider themselves actively engaged in the guitting process. (Grade A, Levels Ia & Ib) **NZGG** Arrange appropriate follow-up for all smokers who are: (2002)not considering quitting planning to quit but not soon ready to guit within the next month and those who have recently quit as relapse prevention or for those who have recently relapsed. Arrange follow-up (in person or by phone) with smokers who are ready to quit: first follow-up within the first week

second follow-up within the first month

reinforce staying quit during visits in the first year postcessation Follow-up by nurses, community workers, and other health workers, as well as doctors, can be effective. Letters/phone calls may be more cost-effective than follow-up visits at the clinic. Actions during follow-up contact — congratulate success. If smoking has occurred, review circumstances and elicit recommitment to total abstinence. Remind patient that a lapse can be used as a learning experience. Identify problems already encountered and anticipate challenges in the immediate future. Assess pharmacotherapy use and problems. Relapse prevention Reinforce the importance of permanent cessation. Health professionals should be aware that personal circumstances may make it difficult for people to stay quit. Make people aware of major triggers, for example, stress and alcohol. Use open-ended questions to identify what precipitated or is precipitating the relapse and encourage active discussion to identify strategies to overcome this. Recently relapsed Ask what precipitated the relapse, and help identify strategies to overcome this in the future. Reaffirm person's ability to quit. Encourage them to set another quit date. Provide them with the free QUITLINE number (0800 778 778 in New Zealand) or other smoking cessation support. USPSTF Arrange follow-up and support (after assisting in quitting). (2003)TREATMENT ELEMENTS Counseling and behavioral therapies PHS Three types of counseling and behavioral therapies result in higher abstinence rates and should be included in therapies: (1) (2000)providing smokers with practical counseling (problem solving skills/skills training); (2) providing social support as part of treatment; and (3) helping smokers obtain social support outside treatment (Strength of Evidence = B). Aversive smoking interventions (e.g., rapid smoking, rapid

puffing) increase abstinence rates and may be used with smokers who desire such treatment or who have been unsuccessful using other interventions (Strength of Evidence = B).

Proactive telephone counseling, and group and individual counseling formats are effective and should be used in smoking cessation interventions (Strength of Evidence = A).

Smoking cessation interventions that are delivered in multiple formats increase abstinence rates and should be encouraged (Strength of Evidence = A).

UMHS (2001)

Help the patient with a quit plan:

- Set a quit date and record this on patient's chart. Ask the
 patient to mark his/her calendar. Quit date abstinence is a
 strong predictor of long-term success [C].
- Patient should inform family, friends, co-workers of quit plan and request support.
- Have patient remove cigarettes from home, car, and workplace environments.
- Anticipate challenges, particularly during the first critical few weeks (i.e., nicotine withdrawal symptoms).

Consider referral to intensive counseling (multi-session, group or individual). Referral considerations include:

- Multiple, unsuccessful quit attempts initiated by brief intervention
- Increased need for skill building (coping strategies/problem solving), social support, and relapse prevention
- Psychiatric cofactors such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse

Give advice on successful quitting.

Provide supplemental educational materials.

SINGAPORE MOH (2002)

Quit plan:

Prepare the patient to stop smoking by setting a quit date. Inform family, friends and colleagues about intention to quit and request understanding and support. Anticipate challenges to the planned quit attempt, particularly during the critical first few weeks. Remove tobacco products from the environment. Help patient choose from several options to stop.

Options to stop smoking:

	 Patient stops on his own with minimal assistance Patient stops with your assistance and follow up. Patient is referred to a dedicated smoking cessation programme
NZGG (2002)	 Bet a quit date. Tell family, friends and co-workers about quitting and request understanding and support. Anticipate challenges to planned quit attempt. Remove tobacco product from the environment. Provide practical counselling (problem solving/skills training): Total abstinence is essential. "Not even a single puff after the quit date". Identify what helped and what hurt in previous quit attempts. Discuss challenges/triggers and how patient will successfully overcome them. Since alcohol can trigger relapse, the patient should consider limiting/abstaining from alcohol while quitting. Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or not smoke in their presence. Provide support and assist patient to gain support in their environment. If a patient is a member of a special high-risk population (for example adolescent, pregnant smoker) consider providing additional information and support.
USPSTF (2003)	Helpful aspects of counseling include providing problem-solving guidance for smokers to develop a plan to quit and to overcome common barriers to quitting and providing social support within and outside of treatment. Common practices that complement this framework include motivational interviewing, the 5 R's used to treat tobacco use (relevance, risks, rewards, roadblocks, repetition), assessing readiness to change, and more intensive counseling and/or referrals for quitters needing extra help. Telephone "quitlines" have also been found to be an effective adjunct to counseling or medical therapy.
	Adjunctive pharmacotherapy
PHS (2000)	All patients attempting to quit should be encouraged to use effective pharmacotherapies for smoking cessation except in the

presence of special circumstances (Strength of Evidence = A).

Long-term smoking cessation pharmacotherapy should be considered as a strategy to reduce the likelihood of relapse.

The following first-line medications should be considered except in cases of contraindications (Strength of Evidence for all medications = A).

- Bupropion SR (Sustained release bupropion)
- Nicotine gum
- Nicotine inhaler
- Nicotine nasal spray
- Nicotine patch

The following second-line medications should be considered for use on a case-by-case basis after first line treatments have been used or considered:

- Clonidine (Strength of Evidence = A)
- Nortriptyline (Strength of Evidence = B)
- Combination nicotine replacement therapy (Strength of Evidence = B)

Over-the-Counter Therapy:

Over-the-counter nicotine patch therapy is more efficacious than placebo and its use should be encouraged (Strength of Evidence = B).

Combination Therapy

Combining the nicotine patch with a self-administered form of nicotine replacement therapy (either the nicotine gum or nicotine nasal spray) is more efficacious than a single form of nicotine replacement, and patients should be encouraged to use such combined treatments if they are unable to quit using a single type of first-line pharmacotherapy. (Strength of Evidence = B)

UMHS (2001)

Both nicotine replacement therapy (NRT) and bupropion hydrochloride (Zyban) have been shown to significantly improve cessation rates [A]. Therefore, pharmacologic therapy should be recommended to all patients except in the presence of special circumstances (see <u>Considerations in Special Populations</u> below). At the time of publication of the 2001 UMHS guideline, bupropion hydrochloride was the only non-nicotine product with FDA approval for smoking cessation.

Non-FDA approved agents with potential benefit in smoking cessation include nortriptyline and clonidine. These drugs may

best be used as second-line agents when patients cannot take or do not wish to take either NRT or bupropion [D]. Combination Therapy Given the additional cost of dual therapies (e.g., patch plus gum; patch plus inhaler; patch plus nasal spray) and limited benefit, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts. SINGAPORE NRT is effective and safe for smoking cessation (Abelin et al., 1989; Bohadana et al., 2000; Dale et al., 1995; Hjalmarson et MOH (2002)al., 1997; Hurt et al., 1994; Lewis et al., 1998; Silagy et al., 1994; Silagy et al., 2000; Tonnesen et al., 1993). (Grade A. Level Ia) At the time of the publication of this 2002 guideline, available NRT products in Singapore were the nicotine patch and inhaler. There is no difference in efficacy between various forms of nicotine replacement (Gourlay et al., 1995; Hjalmarson et al., 1997; Hurt et al., 1994; Sachs, Sawe, & Leischow, 1993; Silagy et al., 2000). (Grade A, Level Ib) Bupropion Slow-Release (SR) is safe and effective for smoking cessation. (Grade A, Level Ib) Although current data suggest that clonidine and nortryptiline may be useful in smoking cessation, they should be used only when first line therapies fail. They have significant side effects and should be used only by those who are well versed in their use. (Grade C, Level IV) Combination Therapy Studies with combination NRT suggest improvement in efficacy over single NRT over a short-term period (Bohadana et al., 2000; Blondal et al., 1999). However, results over medium-term (1 year) are variable. Further studies are therefore required. (Grade A, Level Ib) **NZGG** Encourage NRT except under exceptional circumstances. Discuss NRT with patients. Explain how these medicines increase (2002)smoking cessation success and decrease withdrawal symptoms. At the time of the publication of this guideline in 2002, NRT was available in New Zealand both over-the-counter at pharmacies

and from the Quitline and authorized nicotine patch and gum providers. NRT in New Zealand is available as nicotine patches and gum (over- the-counter), nicotine nasal spray (prescription

medicine), and nicotine inhaler (pharmacist only).

NRT is effective for addicted smokers (more than 10 cigarettes per day) who are motivated to quit, especially when used as an adjunct to counselling/support with organised follow-up.

Inform NRT users not to smoke at all while using NRT and provide with copy of relevant "information sheet."

If previous failure or contraindication to NRT, discuss use of bupropion or nortriptyline.

Combination Therapy

Combination NRT appears to have the potential to provide effective treatment of tobacco dependence in people whose dependence is refractory to monotherapy with NRT. There is currently insufficient evidence to recommend the use of NRT with bupropion or nortriptyline in combination.

USPSTF (2003)

FDA-approved pharmacotherapy that has been identified as safe and effective for treating tobacco dependence includes several forms of NRT (i.e., nicotine gum, nicotine transdermal patches, nicotine inhaler, and nicotine nasal spray) and sustained-release bupropion. Other medications, including clonidine and nortriptyline, have been found to be efficacious and may be considered.

Combination Therapy

There are fair quality studies showing that combining the nicotine patch with either the gum or nasal spray is more efficacious than using a single form of nicotine replacement therapy alone.

CONSIDERATIONS IN SPECIAL POPULATIONS

Pregnancy and second-hand smoke exposure in infants and children

PHS (2000)

Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered extended or augmented psychosocial interventions that exceed minimal advice to quit (Strength of Evidence = A).

Clinicians should offer effective smoking cessation interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy (Strength of Evidence = B).

Pharmacotherapy should be considered when a pregnant woman

	is otherwise unable to quit, and when the likelihood of quitting, with its potential benefits, outweighs the risks of the pharmacotherapy and potential continued smoking (Strength of Evidence = C). Clinicians in a pediatric setting should offer smoking cessation advice and interventions to parents to limit children's exposure to second-hand smoke (Strength of Evidence = B).
UMHS (2001)	Intensive counseling interventions increase quit rates during pregnancy [A]. If intensive counseling is not possible, brief inoffice counseling still has a beneficial effect and should be offered. No studies have addressed the safety of nicotine replacement therapy or bupropion hydrochloride in pregnancy.
SINGAPORE MOH (2002)	 Previous animal studies had associated nicotine with fetal neural abnormalities. Nicotine had also been shown to affect uteroplacental circulation and could contribute to fetal hypoxia. (Benowitz, 1991) On the other hand, serum nicotine levels are higher in active smokers compared to those receiving NRT. The efficacy of smoking cessation pharmacotherapy in pregnancy has not been tested. Also, its effect on pregnancy is unknown. As there is lack of data in pregnancy, it must be used with great caution. Pregnant smokers should be encouraged to stop smoking and psychosocial interventions should be used if necessary. If this fails, physicians may consider pharmacotherapy on an individual basis, after risk and benefit of such a therapy has been discussed with the patient. (Fiore et al., 2000) Grade C, Level IV
NZGG (2002)	 Encourage pregnant women who smoke to quit, and those who have quit to remain non-smokers after delivery. Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective smoking cessation interventions to pregnant women at their prenatal visit as well as throughout their course of pregnancy. Give the free QUITLINE number (0800 778 778 in New Zealand), contact details of free services for pregnant women, Aukati Kai Paipa Smoking Cessation Services and NRT Exchange Card Providers in their locality. Self-help manuals have been shown to be helpful in this group. Most pregnant women who quit smoking while pregnant

- begin again after delivery—intervene with new parents often. Discuss nicotine delivery through breast milk.
- NRT should be considered when a pregnant/lactating woman is unable to quit, and when the likelihood of quitting, with its potential benefits, outweighs the risks of NRT and potential continued smoking. Keep in mind that the risks for the mother and fetus associated with smoking are greater than those associated with NRT use.
- Ask caregivers and parents about exposure to second-hand smoke at Well Child visits, and give parents smoking cessation advice. Discuss the relationship of second-hand smoke to illness at potentially related acute care visits, such as asthma, otitis media, and bronchiolitis.

USPSTF (2003)

The USPSTF strongly recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke (A recommendation).

The USPSTF found good evidence that extended or augmented smoking cessation counseling (5-15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy, and leads to increased birth weights. Although relapse rates are high in the post-partum period, the USPSTF concluded that reducing smoking during pregnancy is likely to have substantial health benefits both for the baby and the expectant mother. The USPSTF concluded that the benefits of smoking cessation counseling outweigh any potential harms.

There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweighs the risks of the therapy and continued smoking.

Children and adolescents: screening and prevention of initiation of smoking

PHS (2000)

Clinicians should screen pediatric and adolescent patients and their parents for tobacco use and provide a strong message regarding the importance of totally abstaining from tobacco use (Strength of Evidence = C).

Because of the importance of primary prevention in children and adolescents, clinicians should pay particular attention to delivering prevention messages to this population.

UMHS (2001)	No recommendations offered.
SINGAPORE MOH (2002)	No recommendations offered.
NZGG (2002)	Ask children over the age of 10, "Have you ever smoked a cigarette?"
	POSITIVELY REINFORCE non-smoking, particularly with adolescents.
USPSTF (2003)	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents (I recommendation).
	The USPSTF found limited evidence that screening and counseling children and adolescents in the primary care setting are effective in either preventing initiation or promoting cessation of tobacco use.
Children and a	adolescents: counseling and treatment of tobacco-dependence
PHS (2000)	Counseling and behavioral interventions shown to be effective with adults should be considered with children and adolescents. The content of these interventions should be modified to be developmentally appropriate (Strength of Evidence = C).
	When treating adolescents, clinicians may consider prescriptions for bupropion SR or NRT when there is evidence of nicotine dependence and desire to quit (Strength of Evidence = C).
UMHS (2001)	The treatment strategies described above for adults will apply to most adolescents who smoke. Clinicians should personalize the encounter to the individual adolescent's situation. NRT may be considered. Bupropion has been studied only in adults.
SINGAPORE MOH (2002)	No recommendations offered.
NZGG (2002)	No cessation programme for teen smokers has been shown to work, so prevention is the key (e.g., repeated positive reinforcement of abstinence).
	Counselling and behavioural interventions shown to be effective with adults should be considered for use with children and adolescents. The content of these interventions should be

	modified to be developmentally appropriate.
USPSTF (2003)	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents (I recommendation). The USPSTF found limited evidence that screening and counseling children and adolescents in the primary care setting are effective in either preventing initiation or promoting cessation of tobacco use. The USPSTF found that school- and classroom-
	based smoking cessation programs may be more effective than no intervention among tobacco users who attend these programs. As with tobacco cessation programs for adults in the community setting, programs with a greater number of counseling sessions and increasing intensity of follow-up had higher quit rates.
	There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy in children or adolescents.
	oncerns, racial/ethnic minorities, patients with psychiatric cofactors, older smokers, and hospitalized patients
PHS (2000)	Gender concerns
, ,	The same smoking cessation treatments are effective for both men and women. Therefore, except in the case of the pregnant smoker, the same interventions can be used with both men and women (Strength of Evidence = B). Women may face different stressors and barriers to quitting that may be addressed in treatment. These include greater likelihood of depression, greater weight control concerns, hormonal cycles, and others.
	Racial and Ethnic Minorities
	Smoking cessation treatments have been shown to be effective across different racial and ethnic minorities. Therefore, members of racial and ethnic minorities should be provided treatments shown to be effective in the original guideline (Strength of Evidence = A).
	Whenever possible, tobacco dependence treatments should be modified or tailored to be appropriate for the ethnic or racial populations with which they are used (Strength of Evidence = C).
	Psychiatric cofactors
	Smokers with comorbid psychiatric conditions should be provided

smoking cessation treatments identified as effective (Strength of Evidence = C).

Bupropion SR and nortriptyline, efficacious treatments for smoking cessation in the general population, also are effective in treating depression. Therefore, bupropion SR and nortriptyline should be especially considered for the treatment of tobacco dependence in smokers with current or past history of depression (Strength of Evidence = C).

Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependency. Therefore, smokers receiving treatment for chemical dependency should be provided smoking cessation treatments shown to be effective, including both counseling and pharmacotherapy (Strength of Evidence = C).

Older smokers

Smoking cessation treatments have been shown to be effective for older adults. Therefore, older smokers should be provided smoking cessation treatments shown to be effective (Strength of Evidence = A).

Hospitalized Smokers

Smoking cessation treatments have been shown to be effective for hospitalized patients. Therefore, hospitalized patients should be provided smoking cessation treatments shown to be effective (Strength of Evidence = B).

UMHS (2001)

Gender concerns

Smoking cessation treatments are shown to benefit both women and men [B]. Two studies suggest that some treatments are less efficacious in women than in men. Women may face different stressors and barriers to quitting (e.g., greater likelihood of depression, greater weight control concerns, and hormonal cycle). This research suggests cessation programs that address these issues would be more effective in treating women [D].

Racial/ethnic minorities.

Smoking cessation treatment has been shown to be effective across both racial and ethnic minorities [A]. Little research has examined intervention specifically designed for a particular ethnic or racial group; however, it is recommended that, when possible, smoking cessation treatment should be tailored to the specific ethnic or racial population with which they are used [C].

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	Psychiatric cofactors
	If presence of psychiatric cofactors, such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse, strongly consider referral to intensive counseling [B]. Treatment of cofactors must be undertaken in preparation for smoking cessation.
	Older smokers
	Smoking cessation treatment has been shown to be effective for older adults and should be provided [A]. Due to particular concerns of this population (e.g., mobility issues) the use of proactive telephone counseling appears to be promising as a treatment modality.
	Hospitalized smokers
	A few studies comparing augmented smoking cessation with usual care of hospitalized patients suggest smoking cessation treatment to be effective [B]. Hospitalization should be used as a springboard to promote smoking cessation.
SINGAPORE MOH (2002)	No recommendations offered.
NZGG (2002)	Maori are more likely to be in an environment with other smokers, which may make quitting more difficult. International evidence demonstrates that quit support initiatives have been less successful among lower socioeconomic groups. There are a number of kaupapa Maori cessation services that provide Maori with excellent support (e.g., Aukati Kai Paipa and Noho Marae). Consider referral to culturally appropriate providers where possible. The QUITLINE (0800 778 778 in New Zealand) provides Maori advisors. Also consider providing contact details of Aukati Kai Paipa and other Maori smoking cessation services and NRT Exchange Card Providers in their area. Smokers with mental health problems Smokers should be asked about mental health problems and other chemical use, and referred to counsellors, mental health services, or drug and alcohol services if indicated, in addition to being encouraged to quit. Smokers with mental health problems
	should be provided with effective smoking cessation treatments. Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependency. Therefore,

	smokers receiving treatment for chemical dependency should be provided with effective smoking cessation treatments, including both counselling and pharmacotherapy.
	Hospitalised smokers
	A hospitalisation provides a powerful opportunity to quit. Hospitalised patients are forced to cut down or quit and may be more motivated to remain so after discharge. Consider prescribing NRT during hospital stay.
USPSTF (2003)	No recommendations offered.

	TABLE 3: BENEFITS AND HARMS
	POTENTI AL BENEFITS
PHS (2000)	 Assessment and treatment of tobacco use and dependence may: Enhance the rates of successful tobacco cessation Decrease the incidence of medical illnesses related to tobacco use Decrease the number of deaths related to tobacco use
UMHS (2001)	Effective interventions and strategies are provided that could help health care providers assist patients in smoking cessation.
SINGAPORE MOH (2002)	 It is beneficial to stop smoking at any age as it has major and immediate health benefits even for smokers who have smoked for many years. Within two days of quitting, the sensations of smell and taste are enhanced. Within two weeks to three months of quitting, circulation improves and lung function increases by up to 30%. The excess risk of heart disease is reduced by half within one year of stopping smoking. Within five years, the risk of heart disease reduces to the level of non-smokers. In those with existing heart disease, smoking cessation reduces the risk of recurrent infarction or death by half. The risk of lung cancer is reduced by 50 to 70% after 10 years of abstinence from smoking and continues to decline thereafter. Women who stop smoking before or during the first trimester of pregnancy reduce the risk to their baby to a level comparable to that of women who have never smoked. The incidence of babies born with low birth weight could

	potentially be reduced by 25% if pregnant women do not smoke during pregnancy.
NZGG (2002)	 It is beneficial to stop smoking at any age. The earlier smoking is stopped, the greater the health gain. Smoking cessation has major and immediate health benefits for smokers of all ages. Former smokers have fewer days of illness, fewer health complaints, and view themselves as healthier. Within one day of quitting, the chance of a heart attack decreases. Within two days of quitting, smell and taste are enhanced. Within two weeks to three months of quitting, circulation improves and lung function increases by up to 30 percent. Excess risk of heart disease is reduced by half after one year's abstinence. The risk of a major coronary event reduces to the level of a never smoker within five years. In those with existing heart disease, cessation reduces the risk of recurrent infarction or death by half. Former smokers live longer: after 10 to 15 years' abstinence, the risk of dying almost returns to that of people who never smoked. Smoking cessation at all ages, including in older people, reduces risk of premature death. Men who smoke are 17 times more likely than non-smokers to develop lung cancer. After 10 years' abstinence, former smokers' risk is only 30 to 50 percent that of continuing smokers, and continues to decline. Women who stop smoking before or during the first trimester of pregnancy reduce risks to their baby to a level comparable to that of women who have never smoked. Around one in four low birth weight infants could be prevented by eliminating smoking during pregnancy. The average weight gain of three kg and the adverse temporary psychological effects of quitting are far outweighed by the health benefits.
USPSTF (2003)	Smoking Cessation Benefits There is good quality evidence that smoking cessation lowers the risk for heart disease, stroke, and lung disease.
	Effectiveness of Counseling
	The USPSTF found good quality evidence examining the efficacy of various levels of intensity of tobacco cessation counseling by clinicians based on a meta-analysis of 43 studies. Compared with no intervention, minimal counseling, lasting less than 3 minutes, has been shown to increase overall tobacco abstinence rates.

Increasing session length and frequency increased efficacy in a dose-response manner. There is limited evidence to determine the optimal duration and periodicity of tobacco counseling interventions.

Pregnancy-tailored Counseling

A meta-analysis of 7 studies found that abstinence rates were higher (16.8% vs. 6.6%) for pregnant smokers receiving pregnancy-tailored counseling and self-help materials compared with pregnant smokers receiving brief counseling or "usual care."

Counseling for Children/Adolescents

The USPSTF found limited evidence of the efficacy of counseling children or adolescents in the clinical primary care setting, but found that school- and classroom-based smoking cessation programs may be more effective than no intervention among tobacco users who attend these programs. As with tobacco cessation programs for adults in the community setting, programs with a greater number of counseling sessions and increasing intensity of follow-up had higher quit rates.

Effectiveness of Pharmacotherapy

Several FDA-approved pharmacotherapies have been identified as safe and effective in helping adults to quit smoking.

- Nicotine products, including nicotine gum, transdermal patch, nicotine nasal spray, and nicotine inhaler, have all been studied in comparison with placebo. There are good quality studies to support the abstinence rates among people who use these products compared with those who do not: 18 to 31% versus 10 to 17%. There are fair quality studies showing that combining the nicotine patch with either the gum or nasal spray is more efficacious than using a single form of nicotine replacement therapy alone.
- Sustained-release bupropion has been shown to be efficacious compared with placebo, with an estimated cessation rate of 23 to 38% compared with 17%.
- Other pharmacotherapies, including clonidine and nortriptyline, have been shown to result in higher smoking cessation rates when compared with placebo, although their use may be limited by side effects.

	POTENTI AL HARMS	
PHS (2000)	Weight gain of as much as 30 pounds occurs in up to 10% of	

quitters.

Exacerbation of comorbid psychiatric conditions may occur following cessation of tobacco use.

Common side effects and their reported incidence for pharmacological agents approved by the U.S. Food and Drug Administration (FDA) for smoking cessation include the following:

- Bupropion SR: insomnia (35-40%) and dry mouth (10%)
- Nicotine inhaler: local irritation in the mouth and throat (40%), coughing (32%), and rhinitis
- Nicotine nasal spray: nasal/airway irritation and reactions (94%), dependency (15-20%)
- Transdermal nicotine (the nicotine patch): local skin reaction (50%) and insomnia
- Nicotine chewing gum: mouth soreness, hiccups, dyspepsia, and jaw ache

Common side effects and their reported incidence of pharmacologic agents not FDA approved for smoking cessation:

- Clonidine: dry mouth (40%), drowsiness (33%), dizziness (16%), sedation (10%), and constipation (10%)
- Nortriptyline: sedation, dry mouth (64-78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%)

UMHS (2001)

Side effects of medications may occur and include the following:

- Transdermal nicotine patch. Skin reactions such as pruritus, edema, rash; sleep disturbance
- Nicotine gum (polacrilex). Jaw fatigue, hiccups, belching, and nausea
- Nicotine nasal spray. Nasal irritation/rhinorrhea (98% of patients), sneeze, cough. Severity of effects decrease after first week.
- Nicotine inhaler. Cough, mouth and throat irritation
- Bupropion hydrochloride SR (Zyban). Insomnia and dry mouth
- Clonidine. Dry mouth and sedation
- Nortriptyline. Dry mouth

No studies have addressed the safety of nicotine replacement therapy or bupropion hydrochloride in pregnancy. The FDA pregnancy risk categories are: Zyban — category B, nicotine transdermal, spray and inhaler — category D, nicotine gum — category C.

	Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.
SINGAPORE MOH (2002)	Nicotine Patch: Skin irritation such as itch and rash caused by direct contact is the most common side effect. Other side effects include nausea, vomiting, headache, insomnia, and nightmares.
	Nicotine Inhaler: Main side effects are irritation in the mouth and throat and coughing. Other uncommon side effects listed in the product insert include nausea, vomiting, heartburn, nasal congestion, sinusitis, headache, and dizziness.
	Bupropion Hydrochloride Slow-Release: Adverse drug reactions reported to the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) included myocardial infarction, seizures, hypoglycaemia, allergic reactions, nausea, anxiety, insomnia, and dizziness.
NZGG (2002)	Smoking cessation Weight gain
	Nicotine Replacement Therapy (NRT): After overdose, upset stomach/abdominal pain, nausea/vomiting, diarrhoea, dizziness, tachycardia, change in hearing/vision, bad headache, flushing, confusion, and hypotension may occur. Withdrawal symptoms (underdose) include craving, irritability, anxiety, sleep disturbance, impaired concentration, hunger, weight gain, and depression. Dependence can also occur.
	Manufacturers' information states that nicotine passes to the fetus and affects its breathing movements and circulation, and that nicotine passes freely into breast milk in quantities that may affect the child even with therapeutic doses and that ideally nicotine should be avoided during breast-feeding.
	Bupropion: Seizures, drowsiness, loss of consciousness, and other undesirable effects can occur. The safety and efficacy of bupropion for patients under 18 years of age or for use in pregnancy has not been established.
	Nortriptyline: Sometimes causes sedation, constipation, urinary retention, and cardiac problems and when taken as an overdose could be fatal. The most common side effect in trials was dry mouth.
USPSTF (2003)	There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweighs the risks of the therapy and continued smoking. Likewise, there is little evidence

on the safety and efficacy of tobacco cessation pharmacotherapy in children or adolescents.

ТАВ	LE 4. EVI DENCE RATING SCHEMES AND REFERENCES
PHS (2000)	Definitions of Strength of Evidence Grades: A. Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings. B. Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, either few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation. C. Reserved for important clinical situations where the panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials. The availability of randomized clinical trials was not considered in economic recommendations. The panel declined to make recommendations when there was no relevant evidence or the evidence was too weak or inconsistent.
UMHS (2001)	Levels of evidence reflect the best available literature in support of an intervention or test: A. Randomized controlled trials B. Controlled trials, no randomization C. Observational trials D. Opinion of expert panel
SINGAPORE MOH (2002)	Grades of Recommendation Grade A (evidence levels Ia, Ib) Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation Grade B (evidence levels IIa, IIb, III) Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation Grade C (evidence level IV) Requires evidence obtained from

expert committee reports of opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality

GPP (good practice points) Recommended best practice based on the clinical experience of the guideline development group

Levels of Evidence

La Evidence obtained from meta-analysis of randomised controlled trials

Ib Evidence obtained from at least one randomised controlled trial

II a Evidence obtained from at least one well-designed controlled study without randomisation

II b Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

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NZGG (2002)	Evidence quality was graded using The US Preventive Services Task Force grading system. I Evidence obtained from at least one properly randomised controlled trial (RCT) II-I Evidence obtained from well-designed controlled trials without randomisation II-II Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group II-III Evidence obtained from multiple time series with or without intervention III Opinions of respected authorities, based on clinical experience
USPSTF (2003)	Definitions

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

Α

The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

В

The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

1

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly

assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

GUI DELI NE CONTENT COMPARI SON

The Public Health Service (PHS), University of Michigan Health System (UMHS), Singapore Ministry of Health (MOH), New Zealand Guideline Group (NZGG), and United States Preventive Services Task Force (USPSTF) present recommendations for tobacco use cessation and prevention. The organizations provide explicit reasoning behind their judgments and rate the evidence upon which their recommendations are based.

PHS cites the 1996 Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]) guideline (currently archived on the National Guideline Clearinghouse [NGC] Web site), which reflected the scientific literature available between 1974 and 1994, as well as additional studies. UMHS utilized the literature searches from both the archived AHRQ guideline and the 2000 PHS guideline, but also supplemented the supporting evidence for its recommendations with subsequently published information. The USPSTF likewise based its recommendations on the evidence provided in the PHS document including more recently published literature. NZGG frequently compares its recommendations with those of PHS, and Singapore MOH also cites the PHS guideline as a reference in its guideline.

Although all groups provide recommendations on identification of tobacco users and the benefits of counseling and adjunctive pharmacologic treatment for tobacco use, the PHS guideline gives a more extensive review and is more comprehensive than the others. PHS presents detailed outlines for both brief and intensive strategies to be used by clinicians for tobacco use intervention. In addition, PHS offers recommendations concerning clinician training in effective tobacco use treatments. NZGG likewise, provides smoking cessation training information for health professionals.

The most notable difference in content between PHS and the other guidelines, however, is that PHS provides specific recommendations for health care administrators, insurers, and purchasers in treating tobacco dependence. PHS argues that tobacco intervention efforts need to be expanded beyond individual clinicians for two reasons. First, individual efforts have yielded disappointing results in the past (clinicians have been failing to advise and assist their patients in quitting tobacco use). Secondly, Americans are receiving more of their health care in managed care settings. PHS identifies a number of institutional policies that would facilitate these treatment interventions.

Areas of Agreement

The recommendations for tobacco use cessation and prevention are in almost total concurrence for all five guideline groups. The "Five A" behavioral counseling framework of asking (identifying users), advising (urging users to quit), assessing (determining users' willingness to quit), assisting (through counseling or drug therapy), and arranging for follow-up is universally recommended. NZGG deviates slightly from this approach by "assessing" patients' willingness to quit before offering "advice".

Identification and Documentation of Tobacco Users

The guidelines are in general agreement regarding the need to identify tobacco users during routine clinic visits. Most groups recommend the use of a chart or sticker system to label a patient as a user or former user of tobacco.

Benefits of Counseling

All of the guidelines agree on the effectiveness of counseling as a means for clinicians to modify behavior and address tobacco dependence in their patients. All guidelines agree that advice to patients should be "clear," "strong," and "personalized" and should include a discussion of the health benefits of quitting, self-help materials, and referral to community groups, if necessary. Each of the guidelines also agrees that patients who do not wish to quit should receive motivational interventions (e.g., the 5 R's: relevance, risks, rewards, roadblocks, and repetition). The importance of frequent and/or intensive counseling is also stressed by all of the organizations. In particular, the dose-response relationship between treatment intensity and abstinence from tobacco use is emphasized.

Adjunctive Pharmacologic Therapy

The use of nicotine replacement therapy (NRT) as an adjunct to counseling is endorsed by all five guideline groups, except in special circumstances. Bupropion is also recommended by all groups as either first-line or second-line medication. Nortriptyline is recognized as a second-line treatment by all five groups. The use of clonidine as second-line therapy is discussed under "areas of differences" below.

There is also general agreement between the groups with respect to the efficacy of combination NRT. For instance, the PHS guideline notes that combining the nicotine patch with a self-administered form of NRT (gum or nasal spray) is more

efficacious than a single form of NRT. UMHS, NZGG, Singapore MOH, and USPSTF likewise note that studies with combination NRT suggest improved efficacy compared with single forms of NRT. UMHS, however notes that, given the additional cost of dual therapies, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts.

There are some disagreements on the use of drug therapy in pregnant women and in children and adolescents, and these differences are also discussed below.

Prevention Strategies

The need for follow-up to prevent and treat relapses is acknowledged by PHS, UMHS, Singapore MOH, and NZGG (USPSTF does not provide any specific recommendations in this area).

PHS and NZGG also emphasize the need for clinicians to help prevent the initiation of tobacco use in children and adolescents through direct counseling or by participation in school-based or community programs.

Passive Smoke Exposure

PHS and NZGG offer specific recommendations on counseling to parents on the need to limit children's exposure to second-hand smoke. UMHS states that the negative effects of passive smoking should be emphasized in trying to motivate smokers to quit.

Gender Concerns, Racial/Ethnic Minorities, Patients with Psychiatric Cofactors, Older Smokers, and Hospitalized Patients

PHS, UHMS, and NZGG address special populations in their guidelines. All three groups agree that these special populations can benefit from many of the same treatments as the general population, but that treatment can be improved by recognizing the problems or concerns of the individual.

Areas of Differences

Adjunctive Pharmacologic Treatment

There are some differences among groups concerning use of clonidine as second-line treatment. PHS, UMHS, and Singapore MOH recommend clonidine as a second-line treatment in patients unwilling or unable to use NRT or bupropion or who fail on first-line therapy. USPSTF states that clonidine may be considered as pharmacotherapy because it results in higher smoking cessation rates when compared with placebo, although its use may be limited by side effects. NZGG, however, does not recommend clonidine even as second-line therapy because of the high incidence of side effects.

Counseling and Treatment of Children and Adolescents

The four groups that provide specific recommendations on counseling and treatment of child and adolescent tobacco users differ somewhat in their

approach. PHS states that counseling must be tailored to the intellectual maturity of the patient and that emphasis should be placed on the short-term negative effects of tobacco use. PHS also recommends adjunctive pharmacotherapy but only when the clinician has evidence that the adolescent is nicotine dependent and is willing to quit. UMHS states that the same counseling and treatment strategies used in adults can be applied to adolescents; however, clinicians should personalize treatment to the individual adolescent. Both NZGG and USPSTF, however, state that there is no evidence for the efficacy of cessation programs in young people. USPSTF therefore does not recommend for or against any routine interventions in the primary care setting for screening or treatment of children or adolescents for tobacco use. NZGG states that because of the limited success of cessation programs in children and adolescents, prevention should be emphasized; however, if counseling and behavioral interventions are used, these interventions should be developmentally appropriate.

Non-Pharmacologic Interventions

PHS differs from other groups in recommending aversive therapies, such as rapid smoking, for patients who desire this treatment or who are unsuccessful with other types of behavioral treatments. NZGG considered aversion therapy in its evidence review but concluded that there was insufficient evidence to recommend it. NZGG cites "significant methodological problems" reported by Cochrane reviewers in the meta-analysis of trials of rapid smoking.

Treatment During Pregnancy

Although all of the groups strongly endorse smoking cessation interventions in pregnant women who smoke, they differ in their recommendations concerning use of pharmacologic therapy. PHS, along with NZGG and Singapore MOH, recommends drug therapy "when the likelihood of quitting and its potential benefits outweigh the risks of the therapy and continued smoking." UMHS makes no recommendation either for or against drug therapy during pregnancy; their guideline states that the safety of NRT and bupropion have not been studied in pregnancy and they refer to the FDA pregnancy risk categories for these drug therapies. USPSTF also cites the lack of evidence on the safety and efficacy of pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, USPSTF makes no recommendations for or against pharmacotherapy during pregnancy, but advises that "pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweigh the risks of the therapy and continued smoking."

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